JCJ

11 6718

CIVIL COVER SHEET

(Rev. 12/07)

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

Charles & Kathleen Youcrett

(b) County of Residence of First Listed Plaintiff YORK
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)
Edward R. Kennett/Dan M. Brookhart, Esq, Atlee, Hall & Brookhart, LLP, 8 N Queen St, Lancaster, PA 17603, (717) 393-9596

DEFENDANTS

DePuy Orthopedics, Inc., DePuy, Inc., Johnson & Johnson International, and Johnson & Johnson

County of Residence of First Listed Defendant Kosciusko County
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☒ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☒ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (**Do not cite jurisdictional statutes unless diversity**): 28 U.S.C. §1332

Brief description of cause: Defective hip prosthesis - strict liability, negligence, breach of warranties, loss of consortium

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE David A. Katz DOCKET NUMBER MDL 1:10 md 2197

DATE 10·24·11

SIGNATURE OF ATTORNEY OF RECORD Edward Kennett

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

OCT 27 2011

JCJ

UNITED STATES DISTRICT COURT

11-CV-6718

11 6718

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: 230 South Kershaw Street York PA 17402

Address of Defendant: 700 Orthopeaic Drive Warsaw IN 46581

Place of Accident, Incident or Transaction: Substantial part of events occured in PA and this distrct and defendants reside in district

(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) unknown at this time Yes☐ No☐

Does this case involve multidistrict litigation possibilities? Yes☐ No☐

RELATED CASE, IF ANY:

Case Number: MDL 1:10 MD 2197 Judge David A Katz Date Terminated:

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? Yes☐ No☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? Yes☒ No☐
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court? Yes☐ No☒
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? Yes☐ No☒

CIVIL: (Place ✔ in ONE CATEGORY ONLY)

A. *Federal Question Cases*:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases (Please specify)

B. *Diversity Jurisdiction Cases*:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☒ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases (Please specify)

ARBITRATION CERTIFICATION

(*Check Appropriate Category*)

I, Edward R Kennett, counsel of record do hereby certify:

☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought.

OCT 27 2011

DATE: 10·24·11 Edward Kennett Attorney-at-Law 69072 Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: _____ _____ Attorney-at-Law _____ Attorney I.D.#

CIV. 609 (6/08)

JCJ

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

Charles and Kathleen Youchett v. DePuy Ortho Inc et al : CIVIL ACTION

11 6718 NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

CMDL (X)

Edward R Kennett		
10·24·11	Dan M Brookhart	Plaintiff
Date	**Attorney-at-law**	**Attorney for**
(717) 393·9596	(717) 393·2138	
Telephone	**FAX Number**	**E-Mail Address**

erkennett@comcast.com
dmbrookhart@comcast.com

(Civ. 660) 10/02

OCT 27 2011

$350.00

JCJ

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

Charles E. and Kathleen A. Youcheff 230 South Kershaw Street York, PA 17402 Plaintiffs vs. DePuy Orthopedics, Inc. 700 Orthopedic Drive Warsaw, IN 46581 Depuy, Inc., a Delaware Corporation Johnson & Johnson International a Delaware Corporation and Johnson & Johnson a New Jersey Corporation Defendant(s)	Civil Action No. 11 6718 Jury Trial Demanded Judge:

COMPLAINT

Nature of the Action

1. Plaintiffs Charles and Kathleen Youcheff bring this action against DePuy Orthopedics, Inc., DePuy, Inc., Johnson & Johnson International, and Johnson & Johnson (hereinafter collectively referred to as "Defendants"), as a result of a defective ASR and ASR XL Acetabular System hip replacement device (hereinafter referred to as "ASR").

2. The ASR device was recalled on August 24, 2010, due to an unacceptably high failure rate and the because the device was known to cause severe injuries.

Statement of Jurisdiction and Venue

3. Jurisdiction over this action exists under 28 U.S.C. §1332 based on diversity of citizenship and an amount in controversy that exceeds $75,000.00 exclusive of interest and costs.

4. Venue is proper in this district pursuant to 28 U.S.C. §1391 because a substantial part of the events giving rise to this claim occurred in Pennsylvania and this district and the defendants reside in this district as defined by 28 U.S.C. §1391(c).

Identity of the Parties

5. Plaintiffs Charles and Kathleen Youcheff reside at 230 South Kershaw Street, York, Pennsylvania 17402 and are citizens of Pennsylvania.

6. Defendant DePuy Orthopedics, Inc., is an Indiana corporation with its principle place of business at 700 Orthopedic Drive, Warsaw, Indiana 46581.

7. Defendant DePuy Orthopedics, Inc., is a wholly owned subsidiary of DePuy, Inc, which is a subsidiary of Johnson & Johnson International, which is a subsidiary of Johnson & Johnson.

8. Defendant DePuy, Inc., is a Delaware corporation.

9. Johnson & Johnson International is a Delaware corporation.

10. Defendant Johnson & Johnson is a New Jersey corporation with its principle place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey, 08933.

11. The term "Defendants" as used herein refers collectively to DePuy Orthopedics, Inc., DePuy, Inc., Johnson & Johnson International, and Johnson & Johnson.

12. At all times material hereto, the Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly, numerous orthopedic products, including the DePuy ASR XL Acetabular System, and were involved in monitoring and reporting adverse events and made decisions regarding the response of the Defendants to these adverse events.

13. At all times material hereto, each of the Defendants was the representative, agent and/or partner of the other Defendants and each was acting in a manner such that acts of one Defendant is attributable to the other Defendants.

Summary of the Facts

14. The ASR device consists of three (3) components: (a) the femoral stem which is inserted into the femur; (2) the femoral head (ball); and (3) the acetabular cup (socket).

15. The ASR is a metal-on-metal device with the ball rotating within a metal acetabular cup.

16. The Defendants submitted §510(k) pre-market notification and obtained marketing approval for the ASR from the FDA under §510(k) of the Act. 21 U.S.C. §360 *et seq.*

17. Since 2003, the Defendants have made various §510(k) pre-market approval submissions to the FDA intended to demonstrate that the ASR devices are substantially equivalent in safety and effectively to an FDA-approved device.

18. On or about March 9, 2004, the Defendants submitted a §510(k) pre-market notification of intent requesting approval for the ASR. See FDA 510(k) No. K040627.

19. On or about August 5, 2005, the Defendants received §510(k) approval for the ASR from the FDA.

20. The §510(k) approval process is regarded as a simplified application process that does not require as extensive review and approval by the FDA as alternative application processes because the entity applying for FDA approval submits that the device to be marketed is substantially equivalent to a legally marketed device.

21. No clinical trials were conducted in connection with the submission of the ASR application process.

22. The Defendants asserted that "the subject device does not raise any new issues of safety or effectiveness."

23. The Defendants promoted the ASR as a device that had several advantages over other hip replacement systems.

24. The Defendants advertised the ASR as being superior than the competition in that the ASR was the device of choice for those wanting to be physically active, for those wanting a high performance hip replacement, and that the system had a strong clinical history and was less prone to wear.

25. Contrary to the Defendants' representations, the ASR was/is prone to premature failure, unacceptably high failure rates when compared with other metal-on-metal prostheses, and causes severe injuries to patients due to metal debris that is released in the patient.

26. The ASR produces large amounts of metallic debris as the metal components wear, and the metal debris causes damage to muscles, tendons, and other soft tissue. The defects also interfere with the intended bone growth and results in high levels of metal in the patients' blood.

27. ASR devices have a significantly higher failure rate than they should due to defects which concentrate the forces in a manner to lead to premature wear, loosening of the prosthesis and metal release.

28. As a result of the defective ASR, patients with ASR hips suffer severe injuries, which include the need for a revision to remove the ASR hip along with other serious injuries as set forth herein.

29. The Defendants failed to adequately test the ASR design before marketing the product.

30. The Defendants knew or should have known that the ASR device was defective, unsafe and not suitable for its intended purpose.

31. The Defendants knew or should have known prior to the August 24, 2010 recall that the ASR was defective and should not be used inside of patients.

32. Between 2006 and 2009 reports of problems associated with the ASR device rose sharply and there was information from Europe and Australia, where the Defendants had been selling the ASR device, that the failure rates were unacceptably high.

33. Additionally, in early March of 2010, the Defendants issued a warning to surgeons in the United States that the ASR device had a higher than expected failure rate. This letter to surgeons in the United States came nearly three months after the Defendants voluntarily withdrew the ASR device from the Australian market in December of 2009. Even so, the Defendants continued to market, promote and sell the ASR device in the United States for about six months until the U.S. recall on August 24, 2010.

34. At all times material hereto, the Defendants had knowledge that the ASR devices had a higher than acceptable failure rate, were not safe and that the ASR was in fact enhancing and causing injuries. Even so, the Defendants refused to concede the product was defective and delayed recalling the ASR device such that ASR devices continued to be used in hip replacement surgeries.

35. On July 9, 2007, Plaintiff Charles Youcheff underwent right hip replacement surgery, during which the ASR was placed.

36. On July 9, 2009, Plaintiff Charles Youcheff also underwent left hip replacement surgery, during which the ASR was placed.

37. Failure of the ASR device resulted in the need for revision surgery for his right hip, which was performed on January 26, 2011.

38. The conduct of the Defendants and the defective ASR device was a legal cause of serious injuries to Plaintiff Charles Youcheff, which include:

(a) undergoing a surgical procedure that would not have been necessary if the ASR was not defective;

(b) undergoing a revision surgery that was more complicated, more invasive and less successful than would have been has the ASR not been defective;

(c) metal poisoning and metalosis due to metal debris from the defective ASR;

(d) lost wages and future earning capacity;

(e) medical expenses and will incur additional medical expenses in the future;

(f) extreme pain and suffering, scarring, disfigurement, embarrassment, humiliation and the loss of the enjoyment of life's pleasures;

(g) being at risk for future medical complications

39. Plaintiffs neither knew nor could have known that the ASR devise was defective until the date of the recall on August 24, 2010.

COUNT I

STRICT LIABILITY

40. The prior paragraphs are incorporated herein.

41. The Defendants are the manufacturer, designer, distributor, seller and/or supplier of ASR devices, including the one supplied to the Plaintiff Charles Youcheff.

42. When the ASR device was implanted in Plaintiff Charles Youcheff, it was unchanged from its condition when it was placed into the stream of commerce by the Defendants.

43. The ASR was and is unsafe for normal and reasonably anticipated use.

44. The ASR was used in the manner for which it was intended and/or in a reasonably foreseeable manner.

45. The ASR was defective and was more dangerous than an ordinary consumer would expect.

46. The ASR was defective in its design and/or manufacture.

47. The ASR did not conform to the representations made by the Defendants.

48. The Defendants failed to warn before implantation of the ASR risks known to the Defendants at that time.

COUNT II

NEGLIGENCE

49. The prior paragraphs are incorporated herein.

50. The Defendants had a duty to use reasonable care in the design, manufacture, construction, formulation, preparation, assembly, testing, marketing, selling, advertising, packaging, labeling, warning about the ASR device.

51. The Defendants had a duty to Plaintiffs since Plaintiff Charles Youcheff had an ASR device implanted.

52. The Defendants negligently designed, manufactured, constructed, formulated, prepared, assembled, tested, marketed, sold, advertised, packaged, labeled, and warned about the ASR device.

53. The ASR is adulterated and/or misbranded as defined by 21 U.S.C. §331 and §333.

54. The Plaintiffs are within the class of persons who are designed to be protected by the Act and regulations promulgated pursuant to it by the FDA, and Plaintiff Charles Youcheff's

injuries are the type of harm these statutes and regulations are designed to prevent. The Defendants, therefore, are negligent *per se*.

55. The Defendants' representations to Plaintiffs regarding the safety and efficacy of the ASR device were false and misleading and Plaintiffs relied upon said representations to their detriment.

COUNT III

BREACH OF EXPRESS AND IMPLIED WARRANTIES

56. The prior paragraphs are incorporated herein.

57. The Defendants expressly warranted that the ASR device was safe and effective.

58. The ASR device carried a warranty implied by law that it would be safe and effective and that it would be reasonably safe for its intended purpose.

59. The ASR device supplied to Plaintiffs did not conform to these express and/or implied representations.

60. Plaintiffs relied upon the express and/or implied warranties in selecting the ASR device and relied on these to their detriment.

COUNT IV

LOSS OF CONSORTIUM

61. The prior paragraphs are incorporated herein.

62. At all times material hereto, Plaintiffs were and are husband and wife.

63. Plaintiff Kathleen Youcheff lost and will continue to lose the services, companionship and consortium of her spouse.

RELIEF REQUESTED

WHEREFORE, Plaintiffs demand judgment against Defendants for damages in excess of $75,000.00, together with prejudgment interest and delay damages, and punitive damages.

Respectfully submitted:

Dated: October 24, 2011

ATLEE, HALL & BROOKHART, LLP

By: _____

Dan M. Brookhart, Esquire
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